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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,566	02/15/2002	Brian Brockway	22570-023001	3298

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FISH & RICHARDSON P.C.
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3735

NOTIFICATION DATE	DELIVERY MODE
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03/16/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/077,566	Applicant(s) BROCKWAY ET AL.	
	Examiner ROBERT L. NASSER	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 44, 48-52, 55 and 60-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 44, 48-52, 55, and 60-77 is/are rejected.
- 7) ☒ Claim(s) 78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/26/2009 has been entered.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 44, 48-52, 55, and 60-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of claims 1, 14, and 67 recite the phrase portion, "wherein the unitary tube structure is in part within the proximal portion of the unitary tube structure and in part within the distal portion of the unitary tube structure." It is unclear how the tube structure can be within itself. It appears from applicant's argument that the phrase meant was meant to recite that the lumen was within the tube structure and the claim will be treated as such.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10-17, 48, 49, 50, 51, 63-70, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al 6296615 in view of Pohndorf et al 5353800 and Brockway et al 4846191.

The examiner notes that Brockway '615 has a patent date of 12/11/2001 and that the current claims have a date of 2/15/2002. Therefore, Brockway '615 is a 102(a) reference and is available for use in a 103 rejection. In addition, the inventorship is different than the current case. As such, Brockway '615 is a reference against the current claims.

Brockway teaches a method of measuring pressure in the left ventricle (see column 12, lines 5-14) by providing a pressure sensor assembly that includes a transducer 142 and a pressure transmitting catheter 120, where the catheter is a unitary structure with a single lumen, and a pressure transmitting substance in the lumen. The distal portion of the catheter has a barrier 130 in an opening to separate the pressure transmitting substance from the environment. In addition, the catheter has a constant thickness and then a thinned down portion and the distal end. According to column 6, lines 10+, while the properties of the catheter may vary, it appears that the materials are uniform throughout the length of the catheter. As such, the thinned down portion is both more flexible than the remainder of the catheter and less crush resistant. Brockway teaches a transvascular approach to the left ventricle. Pohndorf further teaches a method to position a sensor in the left ventricle with an intra luminal approach, where the catheter is passed through the ventricular septum. Hence, it would have been

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obvious to modify Brockway '615 to use such a trans-septal approach, as it is merely the use of a known method for locating a sensor in the left ventricle. As such, when the tip is in the left ventricle, at least a portion of the thicker portion lies and across a wall of the catheter. In addition, the catheter has a degree of flexibility so that it is atraumatic. In addition, Brockway 4846191 shows a similar catheter that has radiused corners. As such, it would have been obvious to modify the combination to round the corners, as it is merely the substitution of one known shape for another. Claim 2 is rejected in that Brockway teaches placing a transmitter with the pressure transducer to wireless transmit information to the exterior of the body. Such an approach has several advantages including reducing infection at the insertion site and allowing the patient freedom of movement. Hence, it would have been obvious to modify the combination to use such a wireless transmitter, to increase patient comfort. Claim 3 is rejected in that Pohndorf teaches an alternate method of accessing a heart chamber, by traversing the entire heart wall. Hence, it would have been obvious to modify the combination to use such an approach, as it is merely the substitution of one known approach for another. Claims 4 and 6 are rejected for the reasons given above. Claim 5 is rejected in that the Pohndorf also catheter can also be positioned across the heart into the right ventricle (see column 5, lines 1-11). Hence, it would have been obvious to use the catheter of Brockway for such a purpose, as it is merely the substitution of one known use of an implanted catheter for another. Claim 7 is rejected in that Pohndorf further teaches in figure 8 that it is known to provide a screw device for securing the assembly, including a housing having the pressure sensor, to the heart wall. Hence, it would have been

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obvious to modify the combination to use such securing means, to provide a more stable environment for measurement. Claims 8 and 12 are rejected in that the housing of the combination would be outside the heart. Claims 10-11 are rejected in that a transluminal approach is a surgical approach. Claims 13-17, and 48-50 are rejected for the reasons given above. . With respect to claim 51, in figure 4, Brockway '191 teaches a barrier recessed from the end of a pressure transmission catheter. Hence, it would have been obvious to modify the combination et al to use such a recessed barrier, as it is merely the substitution of one known functional equivalent catheter for another. Claims 63 and 65 are rejected in that the barrier is a compliant membrane. Claim 64 is rejected in that the barrier of Brockway '615 is a gel. Claim 66 is rejected in that the examiner takes official notice that a piezo-electric transducer is a known pressure sensor. Claims 67-70 and 76-77 are rejected for the reasons given above.

Claims 44 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '615 in view of Pohndorf et al and Brockway et al 191, as applied to claims 1-8, 10-17, 48, 49, 50, 51, 63-70, 76 and 77 above, further in view of Brockway et al 6409674. With respect to claim 44, in column 8, lines 19-57, Brockway '674 teaches the equivalence of a coiled stabilizer like that of Pohndorf and a mesh stabilizer that promotes tissue in growth. As such, it would have been obvious to modify the combination et al to use a mesh stabilizer, as it is merely the substitution of one known equivalent stabilizer for another. As such, the housing would have a tissue in growth promoting surface, i.e. the one facing the direction of the coiled needle, and an in

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growth deterring surface, i.e. the remaining portion of the housing. The device would be positioned as claimed in claim 44. With respect to claim 52, Brockway '674 teaches in column 12, line 37 to column 13 line 4, that it is known to provide a dissolvable material on the tip of a pressure transmission catheter, to ease the transluminal delivery of the pressure sensing device. Hence, it would have been obvious to modify the combination to use a dissolvable material on the tip, to enable easier insertion of the device.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '615 in view of Pohndorf et al in view of Brockway et al '191, as applied to claims 1-8, 10-17, 48, 49, 50, 51, 63-70, 76 and 77 above, further in view of Zheng 6662045. Zheng teaches delivering a device into the heart wall, where an introducer sheath is initially around the device, and then both the sheath and the device are advanced through the wall. Hence, it would have been obvious to modify the above combination to deliver the device using an introducer sheath, as it is merely the substitution of one known deliver device for another.

Claims 60-62 and 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '615 in view of Pohndorf et al in view of Brockway et al '191, as applied to claims 1-8, 10-17, 48, 49, 50, 51, 63-70, 76 and 77 above, further in view of Eigler et al 6328699. Eigler teaches a method of introducing a catheter like that of Brockway into the heart by using a insertion sheath or catheter that is anchored to the septum. Hence, it would have been obvious to modify the combination to use such a catheter, as it is merely the substitution of one known introducing method for another. Eigler teaches a method of introducing a pressure sensing catheter through a

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heart wall including providing a sharpened catheter to pierce the heart wall, passing the pressure sensing catheter through the piercing catheter and into the heart chamber, and then removing the piercing catheter, leaving the sensor in place. Hence, it would have been obvious to modify the combination to use such an insertion method, as it is merely the substitution of one known introducing method for another.

Claim 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 78 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9 and 78 define over the art in that none of the art has the housing with the transducer located inside the heart, as claimed.

Applicant's arguments filed 1/26/2009 have been fully considered but they are moot in view of the reformulated rejection above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
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RLN
March 10, 2009